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10/816,798

04/02/2004

Manne Satyanarayana Reddy

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,798

Applicant(s)

REDDY ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendments and response filed by applicants dated Feb. 14, 2007 have been entered and considered carefully.
2. The rejections of claims 1-7 under 35 USC 112 first and second paragraph are moot in view of the cancellation of claims 1 and 7, and the current amendments in claims 2-6.
3. The rejection of claim 1 under 35 USC 102(b) over Sugimoto et al. '841 is dropped in view of the cancellation of the claim.
4. The rejection of claims 5-6 under 35 USC 102(b) over Imai et al. '864 are now applicable to the currently amended claims 1-6.

Please note that the instant claims being drawn to donepezil hydrochloride crystals having substantially X-ray powder diffraction as depicted in figure 1 is anticipated by figure 3 product of Imai et al. '864. A comparison of substantial diffraction pattern was made in Exhibit I, which is hereby attached for applicant's convenience. Upon similar para-scaling, substantial IR, TG and DSC can be found between the instant figure 2 vs figure 8, instant fig. 3 and fig. 4 vs. figure 13. Substantial patterns can be identified as in Exhibit I. Therefore, anticipation was found for all the claims.

The only difference between the process of claim 6 and the example 18 is the drying of preheating to dissolve the starting material since such is not the critical step in crystallization and the prior art apparently had a "solution" of donepezil free base in ethanol. In addition, in a small section of examples 16-23, the heating step was well delineated in example 23, therefore anticipation was found based on small genus with clearly delineation. Ex parte A 17 USPQ2d 1716.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1625

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imai et al. US 5,985,864 in view of Doelker, Wikipedia Davidovich or US Pharmacopia.

Determination of the scope and content of the prior art (MPEP §2141.01)

Imai et al. ;864 disclosed anticipatory product as claimed in claims 1-5 made by process of claim 16, see figures 3, 8, 13 and examples 18 and 23.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the dependent claims 8-12 wherein variation of solvent system was employed in the process of crystal preparation is generically taught by Imai et al. '841 and exemplified in examples 16-23 wherein the variation of preheating, solvent mixtures, drying temperature were clearly delineated.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the US 5,985,864 reference is in possession of the instantly claimed variations. The well delineated variation in the reference gives clearly guidelines on the suitable conditions one can optimize to obtain the desirable crystal form.

The substantial patterns of physical properties between the prior art and the instant claims have been pointed out. Applicants allege that there are differences between the prior art data and the instantly claimed data. Any discrepancy which are not artifacts between laboratories or experimental conditions must be supported by competent comparisons based on factual evidence. Mere arguments by attorney is entitled to little weight. In re Lindner 173 USPQ 356.

5. Claims 8-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form.

Art Unit: 1625

Please note that the dependent claims are drawn to scope "comprising" alcohol or ether which is broadening of the base claim wherein only alcohol or ether was the solvent.

6. Applicants amendments necessitated the new grounds of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

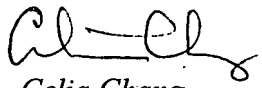
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 3, 2007


Celia Chang
Primary Examiner
Art Unit 1625